Comments on the Supplemental Draft Environmental Impact Statement, Integrated Research Facility,RML, February 2004 Friends of the Bitterroot – Women's Voices for the Earth – Coalition for a Safe Lab

62-50

5. Range of alternatives is inadequate and the No Action Alternative is not studied in detail.

5.1 The NIH's DEIS fails to comply with the NEPA/CEQ Regulations regarding a range of alternatives.

The DEIS failed to develop and/or consider a reasonable range of alternatives.

5.1.1 The NEPA/CEQ alternative section is described as "the heart of the environmental impact statement," 40 CFR 1502.14.

Hence, "[t]he existence of a viable but unexamined alternative renders an environmental impact statement inadequate." (Citizens for a Better Henderson v. Hodel, 786 F.2d 1051, 1057 (9th Cir. 1985))

NEPA provides that all agencies of the Federal Government shall, to the fullest extent possible, "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." (42 U.S.C. 4332(2)(E)); (Idaho Conservation League v. Mumma, 956 F.2d 1508, 1519 (9th Cir. 1992))

5.1.2 The DEIS only analyzes one action alternative.

NIH's DEIS states the following: "Project Alternatives - The only alternative to the Proposed Action discussed in detail in this EIS is the No Action Alternative. Under the No Action Alternative, the Proposed Action would not be implemented." (DEIS S-2) Proposed Action and Alternatives - "Detailed discussions of the following topics are presented in this chapter: The Proposed Action; and, Alternatives to the Proposed Action including the No Action Alternative and Alternatives considered but eliminated from detailed study." (DEIS 2-1)

Decision to be Made: "Based on the environmental analysis and consideration of public comments on the Proposed Action, NIH will decide: • Whether to construct an Integrated Research Facility including a Biosafety Level 4 laboratory at RML;" and "The scope of the Project is confined to issues and potential consequences relevant to the decision. The decision is subject to and would implement direction from higher levels." (DEIS 1-6)

"NIH ... has identified the Proposed Action as the preferred alternative." (DEIS 2-10)

Alternatives Considered But Eliminated From Detailed Study (DEIS 2-9) states: "This section describes alternatives that were eliminated from further review in the EIS." They were eliminated because they were: "considered technically infeasible, provided no environmental advantage" … "or would not meet the purpose and need of the Proposed Action."

Comment	Response
62-50	Please see Section 1.7 where comments on the range of alternatives were addressed. To be viable, an alternative needs to (among other things) meet the purpose and need of the project. There were no issues (unresolved conflicts) identified with the Proposed Action that were not addressed by the No Action Alternative.

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5.1.3 Pubic scoping comments specifically asked that the NIH consider the following reasonable alternatives to the Proposed Action.

5.1.3a Relocate Rocky Mountain Laboratories to a Less Populated Area (DEIS 2-9)
Rational for Dismissing: "This alternative does not meet the purpose and need 'to provide a highly contained and secure intramural laboratory for continuation of research into emerging infectious disease within the budgetary constraints of NIH at the Rocky Mountain Laboratories facility in Hamilton, Montana'. Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility. Construction ... at an alternate site would require additional funding to provide infrastructure and research laboratory support currently in-place at RML." (DEIS 2-10)

5.1.3b Construct Integrated Research Facility (BSL-4) at Alternate Location (DEIS 2-10)
Rational for Dismissing: [Lack of scientific integration; eliminates connected research; would be inefficient and impracticable.] "Additionally, this alternative fails to meet the need for this project, 'to efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through detection, investigation, control, and prevention of disease'." "This alternative also fails to meet the budgetary constraints in the purpose of the Project and the effectiveness and efficiency part of the need for the Project." "Issues addressed through this alternative are also addressed through the No Action Alternative". (DEIS 2-10)

62-51 **5.1.3c NIH's DEIS arbitrarily and capriciously refused to consider reasonable alternatives to the agency's Proposed and Preferred alternative that were suggested by the public during scoping.**

Examples of suggestions made during scoping were to locate the BSL-4 in military installations or locations remote from populations.

5.1.3d The DEIS failed to fully disclose, and failed to take a hard look at the fact that there is an already completed, but not used, BSL-4 lab in Bethesda, Maryland. A recent newspaper article stated the following regarding the unused Bethesda BSL-4 lab: "A Biosafety Level 4 lab was built several years ago on the Bethesda, MD campus of NIH but it has never been used for this purpose. Maryland has a ten-member congressional delegation, more than three times the numerical strength of Montana's contingent. Hundreds of other members of Congress live in Bethesda, an affluent suburb of Washington, D.C." (BIO-FEAR IN THE BITTERROOT VALLEY; Medford Mail Tribune; by Les AuCoin; Environmental News Service 7/14/03)

And, from Dr Fauci's testimony on June 10, 2002, it appears that there are three currently operating BSL-4 facilities in the United States: Atlanta, Georgia; Fort Dietrich, Maryland; and 'one operational in Texas'. Dr Fauci also indicated there were apparently at least two more BSL-4 facilities "planned" to be built at that time; one in Texas and one at the RML in Hamilton, Montana. (Homeland Security: The Federal and Regional

Comment	Response
62-51	Please see Section 1.7 where comments on alternatives were addressed.

Response Field Hearing before the Subcommittee on Environment, Technology, and Standards Committee on Science, House of Representatives, One Hundred Seventh Congress Second Session; June 10, 2000)

5.1.3e The NEPA/CEQ regulations (40 CFR 1500, et seq.) go into substantive detail describing Federal Agency requirements and obligations regarding "alternatives".

1500.2 - POLICY:

> "Federal agencies shall to the fullest extent possible: (b) Implement procedures to make the NEPA process more useful to decisionmakers and the public; ... and to emphasize real environmental issues and alternatives. Environmental impact statements shall be concise, clear, and to the point, and shall be supported by evidence that agencies have made the necessary environmental analyses. (d) Encourage and facilitate public involvement in decisions which affect the quality of the human environment. (e) Use the NEPA process to identify and assess the reasonable alternatives to propose actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment. (f) Use all practicable means, consistent with the requirements of the Act and other essential considerations of national policy, to restore and enhance the quality of the human environment and avoid or minimize any possible adverse effects of their actions upon the quality of the human environment."

1502.1 PURPOSE:

> "The primary purpose of an environmental impact statement is to serve as an action-forcing device to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government. It shall provide full and fair discussion of significant environmental impacts and shall inform decisionmakers and the public of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment. Agencies shall focus on significant environmental issues and alternatives and shall reduce paperwork and the accumulation of extraneous background data. Statements shall be concise, clear, and to the point, and shall be supported by evidence that the agency has made the necessary environmental analyses. An environmental impact statement is more than a disclosure document. It shall be used by Federal officials in conjunction with other relevant material to plan actions and make decisions."

1502.14 ALTERNATIVES INCLUDING THE PROPOSED ACTION:

> "This section is the heart of the environmental impact statement. Based on the information and analysis presented in the sections on the Affected Environment (1502.15) and the Environmental Consequences (1502.16), it should present the environmental impacts of the proposal and the alternatives in comparative form, thus sharply defining the issues and providing a clear basis for choice among options by the decisionmaker and the public. In this section agencies shall: (a) rigorously explore and objectively evaluate all reasonable alternatives, and for alternatives which were eliminated from detailed study, briefly discuss the reasons for their having been eliminated. (b) Devote substantial treatment to each

alternative considered in detail including the proposed action so that reviewers may evaluate their comparative merits. (c) Include reasonable alternatives not within the jurisdiction of the lead agency. (f) Include appropriate mitigation measures not already included in the proposed action or alternatives."

1502.24 METHODOLOGY AND SCIENTIFIC ACCURACY:
"Agencies shall insure the professional integrity, including scientific integrity, of the discussions and analyses in environmental impact statements."

1506.1 LIMITATIONS ON ACTIONS DURING NEPA PROCESS:
"(a) Until an agency issues a record of decision as provided in 1505.2 ... no action concerning the proposal shall be taken which would: (1) Have an adverse environmental impact; or (2) Limit the choice of reasonable alternatives."

62-52 There apparently is an unused existing BSL-4 facility in Maryland, another in Texas is "planned", and it appears that others are being "planned or proposed" around the nation. The DEIS failed to comply with NEPA's requirements by refusing to develop a reasonable range of alternatives.

62-53 The DEIS apparently failed to develop or consider a reasonable range of alternatives, failed to comply with the scoping regulations, and failed to provide an accurate Cost-Benefit Analysis. In doing so, it appears the DEIS is not in compliance with 40 CFR 1500.2, 1502.1, 1502.14, 1502.16, 1502.24, 1506.1, 1502.23, 1501.7, and 1508.25, et seq.

5.2 The NIH dismisses and ignores nearly all citizen suggested mitigation measures.

62-54 **5.2.1 The DEIS does not develop mitigation alternatives suggested in scoping.**
Below is the DEIS mitigation discussion from Section 1.7.1 (DEIS 1-8 and 1-9). The bracketed items notes NIH's response/disposition of the suggested measures by citizens:

"1.7.1.1 Mitigation Measures
Potential mitigation measures raised by those individuals providing comments during scoping include:

• Adoption of pollution prevention strategies to avoid or reduce the amount of pollution generated at the facility. Efforts are described in the *Disposal of Non-Contaminated Material.* **[This recommendation is not, in fact, discussed in the referenced section.]**

• *Waste* that has not come in contact with a biohazardous, radioactive or chemical material is considered non-contaminated and would be disposed of as general waste. This would make up the majority of waste from the facility. **[This confirms what already happens.]**

• Improving parking for workers and visitors during and after construction of the

Comment	Response
62-52	Please see Section 1.7.1 where this comment was addressed.
62-53	A cost/benefit analysis is not required in the CEQ regulations for implementing NEPA.
62-54	Please see Section 1.7.2 where comments on mitigation measures were addressed. Please also see response to comment 62-15.

Integrated Research Facility. This is part of the *Reasonably Foreseeable Actions* as described on page 4-1. **[This was apparently adopted.]**

62-55 • Implementation of a car-pooling program for workers commuting to the RML campus. This measure will not be included in the Proposed Action as parking and traffic are addressed under social issues. **[Refused without comment.]**

62-56 • Adopting a policy of studying only those agents associated with emerging diseases at the Integrated Research Facility, and not agents associated with bioterrorism or biodefense. This is addressed through the *Purpose and Need* section on Chapter 1. **[The referenced chapter states that no weapons grade material will be studied – without any citation to a regulation or other agency commitment. However, this does not answer the recommendation. The recommendation is not discussed. It should also be noted that under recently passed laws, that there are plans to use weapons grade material, but the agency would be prohibited by recently passed antiterrorism laws from disclosing that fact to the public.]**

62-57 • Creation of a citizen oversight committee to monitor activities at the Integrated Research Facility. This measure will not be included in the Proposed Action because monitoring is done by RML for a number of state and federal agencies and the results are made public. The Community Liaison Group, composed of community members, serves to monitor activities at RML. The RML Institutional Biosafety Committee and the Chapter 1 Purpose and Need RML Animal Care and Use Committee also have community representatives. **[This recommendation is ignored. The Community Liaison Group does not monitor the activities of RML and only serves as a forum for formal interactions with the agency related to the proposed alternative.]**

• Improving aesthetics of the campus. This measure is included in the Proposed Action, as well as *Reasonably Foreseeable Actions* as described on page 4-1. Aesthetics were considered in the design of the building, as well as effects analysis. **[This recommendation was apparently adopted.]**

62-58 • Implementation of regular effluent monitoring of air emissions and wastewater discharges are included in *Air Treatment* and *Waste Decontamination* in Chapter 2. **[This recommendation is ignored without comment in the referenced section.]**

62-59 • Use of local contractors for design and construction of the Integrated Research Facility to the greatest extent possible. NIH has hired a national design and engineering firm that specializes in designing and building BSL-4 laboratories. **[This is refused.]**

62-60 • A commitment for direct improvements to the hospital, streets, and emergency response agencies by NIH. This is included in the *Reasonably Foreseeable*

Cont. on next page

Comment	Response
62-55	Please see Section 1.7.2 where comments suggesting carpooling were addressed.
62-56	Please see Section 1.7.2 where comments regarding a policy of studying only those agents associated with emerging diseases were addressed.
62-57	Please see Section 1.7.2 where comments on creation of a citizen oversight committee were addressed.
62-58	Please see Section 1.7.2 where comments on implementation of regular effluent monitoring of air emissions and wastewater discharges were addressed.
62-59	Please see Section 1.7.2 where comments on using local contractors were addressed.

62-60

Actions as described on page 4-1. **[This is ignored.]**

• Noise and light reduction through more landscaping and buffering. This measure is included in the Proposed Action, as well as *Reasonably Foreseeable Actions* as described on page 4-1, and was considered in the design of the building as well as effects analysis. **[This is adopted.]**

• Establishment of a process where neighbors could bring concerns to RML during and after construction of the Integrated Research Facility. This measure was included in the Proposed Action. Meetings with neighborhood representatives would be held regularly before, during, and after construction. In addition, the Community Liaison Group, including local residents, addresses any issue brought to it. **[This is adopted.]**

62-61

• Purchase of homes at fair market value for anyone that requested it within a few blocks of the Integrated Research Facility because of a perceived fear of lost value once the Integrated Research Facility is completed. This measure is not included in the Proposed Action because there is no indication that the Proposed Action will have a negative effect on property values (see Chapter 4). **[The possibility of negative impacts on property values is not mentioned in the referenced section. See comments below in which NIH's contractor bought homes in anticipation of selling them to the government in anticipation of the implementation of the proposed project.]**

62-62

This treatment of citizen's comments again shows bias toward the proposed alternative. The writers of the DEIS attempt to make it look to the reader as if all of the recommended mitigation measures by citizens are discussed. In fact, the mitigation measures that the agency did not choose to adopt are ignored without comment.

5.2.2 The DEIS also ignores mitigation alternatives.

The NIH recognizes a duty to include mitigation in the proposed action.

"In accordance with section 40 CFR 1502.16 (Regulations implementing the Procedural Provisions of NEPA), the following are the required disclosures, and where they can be found:

• Means to mitigate adverse environmental impacts (Chapter 4)." (DEIS 1-2)

A number of scoping comments recommended specific mitigation measures.

"Six percent identified potential mitigation measures," (DEIS1-8).

A look at Section 4 shows that no mitigation measures are proposed or analyzed. The only discussion of mitigation measures is a general reference to mitigation in the Ravalli County Growth Plan.

Comment	Response
62-60	Please see Section 1.7.2 where comments on a commitment for direct improvements were addressed.
62-61	Please see Section 1.7.2 pf the SDEIS where comments on the purchase of homes at fair market value were addressed.
62-62	The responses to comment 62-54 through 62-61, and many others, indicate that comments were not ignored. Section 1.7.2 starts out with how comments were initially included. None of the comments listed above are included in the "Additional mitigation measures" section, but were included in the original DEIS.

CEQ 1502.14 (f) states that a DEIS alternatives should: "Include appropriate mitigation measures not already included in the proposed action or alternatives."

62-63 Yet no alternatives are developed for mitigation.

Additional alternatives must be considered.

5.3 Alternate Locations Must Be Considered.

62-64 NIH is required to consider a reasonable range of alternatives. The alternatives must include considering other locations as well as mitigation measures suggested by citizens and the DEIS analysis itself.

5.3.1 Relocate Rocky Mountain Laboratories to a Less Populated Area (DEIS 2-9)

Rationale for Dismissing

"This alternative does not meet the purpose and need 'to provide a highly contained and secure intramural laboratory for continuation of research into emerging infectious disease within the budgetary constraints of NIH at the Rocky Mountain Laboratories facility in Hamilton, Montana." "Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility." (DEIS 2-10)

5.3.2 Construct Integrated Research Facility (BSL-4) at Alternate Location (DEIS 2-10)

Rationale for Dismissing

[Lack of scientific integration; eliminates connected research; and would be inefficient.] "Additionally, this alternative fails to meet the need for this project, 'to efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through detection, investigation, control, and prevention of disease'." "This alternative also fails to meet the budgetary constraints in the purpose of the Project and the effectiveness and efficiency part of the need for the Project." "Issues addressed through this alternative are also addressed through the No Action Alternative". (DEIS 2-10)

"NIH ... has identified the Proposed Action as the preferred alternative." (DEIS 2-10)

5.3.3 Location Alternatives Should Not Be Dismissed

The General Administration Manual also states:

> 30-30-30 C.: "Alternatives. Environmental impact statements must explore and evaluate reasonable alternatives to the proposed action in terms of their environmental consequences, benefits and costs, and contribution to the underlying purpose or goal. Discussion of alternatives must be sufficiently in-depth to permit a meaningful comparison of alternative courses of action.
>
> 2. Action Alternatives. One or more alternative courses of action directed at achieving the underlying purpose or goal. The environmental impact statement cannot automatically exclude actions:

Comment	Response
62-63	Please see Section 1.7 where comments on alternatives were addressed. Please also see response to comment 62-15.
62-64	Please see Section 1.7.1 where comments on alternatives were addressed.

> Outside the expertise or jurisdiction of Departmental organizations, e.g., examining the possible use of other real properties other than that proposed for transfer by HHS; or
>
> Which only partially achieve an underlying goal or objective, e.g., funding a health care facility at a lower capacity for patient care. However, action alternatives considered must be reasonably available, practicable, and be related to the underlying purpose or goal. An environmental impact statement must include all reasonable alternatives.

In Section 2.2.2.2 (DEIS 2-10) the suggested alternative of "Construct Integrated Research Facility (BSL-4) at Alternate Location" was dismissed for insufficient reasons.

62-65 The first reason stated is that "locating the BSL-4 separate from the rest of RML would eliminate the connected research on projects that use BSL-2 and BSL-3 facilities." The proposed project includes the building of both BSL-2 and BSL-3 facilities, so it is difficult to see how the project if built elsewhere would separate that research. Secondly, two of the potential locations recommended in the scoping process were the NIH campus in Bethesda and the CDC campus in Atlanta. Both campuses already have BSL-2, BSL-3 and even BSL-4 laboratories that the research in the new lab can be connected to, and could benefit from.

62-66 The second reason this alternative was dismissed was because it fails to meet the need "to efficiently and effectively provide a realistic, orderly and comprehensive effort to safeguard the health of the American people through detection, investigation, control and prevention of disease." There is no reason why a lab in Bethesda or Atlanta would not be able to meet this need.

62-67 The last reason for dismissing an alternative location is that it fails to meet "budgetary constraints." It is unacceptable to simply state that it fails to meet "budgetary constraints" without clearly establishing the budget for the project. The only budgetary information in the DEIS is a single statement:

> "Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility." (DEIS 2-10)

62-68 **5.3.4 A full financial analysis for the preferred alternative as was requested specifically in scoping comments is needed to understand the "budgetary constraints" of this authorized expenditure.**

A detailed description of the costs of the preferred alternative proposed in an EIS is absolute standard of disclosure. Similarly, a full financial analysis of other alternatives including construction of the lab at an alternative location and the no-action alternative are also needed for comparison. It is unacceptable to simply state:

> "Construction of the facility at an alternate site would require additional funding to provide infrastructure and research laboratory support currently in-place at RML." (DEIS 2-10)

Cont. on next page

Comment	Response
62-65	Please see Section 1.7.1 where comments on alternatives were addressed.
62-66	Please see Section 1.7.1 where comments on alternatives were addressed.
62-67	Please see Section 1.7.1 where comments requesting more information on the budget and finances were addressed.

62-68 A full financial analysis of the required "additional funding" is needed to justify this claim in the DEIS.

62-69 **5.4 Mitigation Alternatives Must Be Considered.**

The HHS General Administration Manual states:

> "30-50-60 E. Responsibilities. Except for proposals for legislation, OPDIVs/STAFFDIVs shall prepare EISs in two stages: Draft and final. The responsible official will ensure that:
>
> 1. Appropriate mitigation measures are included in the proposed action or alternatives;"

In addition, CEQ 1502.14 requires mitigation alternatives.

5.4.1 Local government financial impact mitigation.

Section 4.2.2 briefly discusses impacts to community safety, but does not analyze the direct and indirect economic effects of these impacts. The section states:

> "Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML." (DEIS 4-7)

62-70 These procedures and protocols will require local emergency response agencies to acquire both new equipment and extensive training. *The costs for this equipment and training are economic effects of the preferred alternative and must be calculated and presented in the Economic Resources Direct and Indirect Effects - Government and Public Finance section (Section 4.3.1.1 DEIS 4-8).*

Mitigation alternatives that would offset these financial impacts to local emergency response agencies should be discussed as well. Mitigation alternatives would include alternatives that offer funding to local emergency response agencies and hospitals to cover the costs of training, drills and equipment.

5.4.2 Safety mitigation.

62-71 Public comments submitted thus far reveal that community safety is one of the greatest concerns of neighbors and nearby residents with respect to the preferred alternative. *A detailed explanation of the mitigation strategies that would be implemented to offset the significant consequences of a release of an agent to the community or environment must be included in this DEIS.*

Section 4.2.1.1 of the DEIS states:

Comment	Response
62-68	More information on the established budget has been included in the "Background" in Chapter 1.
62-69	Please see Section 1.7.2 where comments on mitigation measures were addressed. Please also see response to comment 62-15.
62-70	Please see Section 1.7.3 where comments on community infrastructure were addressed. No mitigation is necessary.
62-71	Please see Section 1.7.3 where comments on the increased threat from the Integrated Research Facility were addressed.

"Numerous means would be employed to control access to agents and the facility and reduce the potential for release of an agent to the environment or community. These include:
- Specialized laboratory construction;
- Employee screening and training;
- Site security;
- Air and wastewater treatment;
- Backup systems; and
- Emergency response." (DEIS 4-5)

Each of these means needs to be described in detail as a mitigative action in the DEIS. In particular, the mitigative action of emergency response (i.e. the emergency plan and protocols) must be included in full in the DEIS.

62-72

5.4.3 Pollution Prevention strategies.

Pollution prevention has been identified as an important mitigation strategy by the Department of Health and Human Services. There should be a significant emphasis on pollution prevention in this DEIS.

The HHS General Administration Manual states the following with regard to pollution prevention:

"30-10-30 Strategy

HHS has adopted and will adhere to a Code of Environmental Management Principles (CEMP) to help achieve the goals of the HHS environmental protection program. As part of the effort to implement these principles throughout HHS, all OPDIVS/STAFFDIVS will integrate the following principles into their environmental protection programs:
1. Management Commitment--Written top management commitment to improved environmental performance by establishing policies which emphasize pollution prevention and the need to ensure compliance with environmental requirements.
2. Compliance Assurance and Pollution Prevention--Proactive programs that aggressively identify and address potential compliance problem areas and utilize pollution prevention approaches to correct deficiencies and improve environmental performance.

30-50-05 Definitions and Acronyms

'Pollution Prevention' includes, but is not limited to, reducing or eliminating hazardous or other polluting inputs, which can contribute to both point and non-point source pollution; modifying manufacturing, maintenance, or other industrial practices; modifying designs; recycling (especially in-process, closed loop recycling); preventing the disposal and transfer of pollution from one media to another; and increasing energy efficiency and conservation. Pollution prevention

Comment	Response
62-72	Please see Section 1.7.2 where comments on pollution prevention strategies were addressed.

> can be implemented at any stage--input, use or generation, and treatment--and may involve any technique--process modification, waste stream segregation, inventory control, good housekeeping or best management practices, employee training, recycling, and substitution. Any reasonable mechanism which successfully avoids, prevents, or reduces pollutant discharges or emissions other than by the traditional method of treating pollution at the discharge end of a pipe or stack should, for purposes of this chapter, be considered pollution prevention.
>
> 30-50-65 Contents of an EIS
>
> C. Pollution Prevention. Pollution prevention should be an important component of mitigation of the adverse impacts of a Federal action. To the extent practicable, pollution prevention considerations should be included in the proposed action and in the reasonable alternatives to the proposal, and should be addressed in the environmental consequences section of the EIS (40 CFR 1502.14(f), 1502.16(h), and 1508.20)."

Unfortunately, the words "pollution prevention" only occur once in the entire document (DEIS1-8) in Section 1.7.1.1. This section refers to a discussion of pollution prevention strategies purported to be discussed in the section titled "Disposal of Non-Contaminated Material" (DEIS 2-8). That entire section reads as follows:

"Disposal of Non-Contaminated Material
Waste that has not come in contact with a biohazardous, radioactive or chemical material is considered non-contaminated and would be disposed of as general waste. This would make up the majority of waste from the facility." (DEIS 2-8)

62-73 *Specific pollution prevention strategies must be developed and discussed in this DEIS.*

5.4.4 Failure to disclose planned noise reduction measures.
Section 4.4.1 of the DEIS states:

> "The Proposed Action would meet RML's new draft noise guidelines. Existing noise sources would continue as described under No Action." (DEIS 4-8)

Section 4.4.2 of the DEIS states:

> "Reasonably foreseeable noise reduction features would result in a slight reduction in noise overall as shown in Table 4-2." (DEIS 4-9)

62-74 The actual noise reduction features however are not described in the DEIS. *These features are mitigative strategies that should be addressed clearly in this section.*

40 CFR 1502.1 states:

Comment	Response
62-73	Please see Section 1.7.2 where comments on pollution prevention were addressed. As noted, DHHS's regulations on the inclusion of pollution prevention applies to "potential compliance problems." No compliance problems would occur under the Proposed Action.
62-74	Please see Section 1.7.2 where comments on noise reduction were addressed.

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> "[Environmental Impact] Statements shall be concise, clear, and to the point, and shall be supported by evidence that the agency has made the necessary environmental analyses."

62-75 Simply stating that noise guidelines will be met and that noise reduction features will reduce noise does not comprise "evidence that has the agency has made the necessary environmental analyses." *If Big Sky Acoustics has completed an analysis for RML it should be described and included as an appendix to the DEIS for public review.*

62-76 According to Table 4-2 (DEIS 4-9) it appears that the emergency generator and the incinerator are the two pieces of equipment on site that contribute the loudest noise. The preferred alternative includes the addition of another emergency generator that must be tested regularly and a significant increase in use of the incinerator. **It must be clarified as to how the preferred action will lead to a decrease in noise levels from the current situation.**

62-77 Secondly, Section 4.4.1.2 (DEIS 4-8) claims that the No Action alternative would lead to no change in noise levels from RML. It is our understanding, from the presentation at a CLG meeting, that RML's draft noise guidelines are being implemented independently of the BSL-4 project. Yet this section implies that without implementing the preferred alternative, RML would not take action to meet the draft noise guidelines. *Please clarify if the noise reduction program - inspired by complaints from the community - is dependent on building the BSL-4. If it is not dependent on the preferred alternative, Section 4.4.1.2 should be changed to reflect the noise improvements that will be conducted regardless to meet the draft noise guidelines.*

5.4.5 Lack of air pollution prevention strategies.

Section 4.7.1 of the DEIS states:

> "Incinerator use is estimated to increase from approximately two to three days a week to three to four days a week." (DEIS 4-13)

62-78 Very clearly the preferred alternative will increase rather than prevent air pollution. Unfortunately, in Section 4.7 **Air Quality Direct and Indirect Impacts** no analysis is given of the exact increase in emissions. Simply stating that the total permit emission allowance will not change is not an analysis of the direct impact. There are emission factors for the incinerator for both criteria and hazardous pollutants, which RML uses to create an emission inventory sent to Montana DEQ each year. *A current emission inventory for all of these pollutants should be in the DEIS along with a comparative expected emission inventory reflecting the increased use of the incinerator.*

An air pollution prevention mitigation alternative for this increased pollution should be included in the DEIS. The most obvious and practicable pollution prevention alternative is to utilize an alternative method of disposal instead of the incinerator. An alternative disposal method is both readily available and inexpensive (i.e. the landfill in nearby

Comment	Response
62-75	The noise analysis was summarized in the DEIS, SDEIS and FEIS and is included in the administrative record, as indicated.
62-76	Please see Section 1.7.3 where comments on the effects of the Proposed Action and noise (and clarification of the analysis) were addressed.
62-77	Please see Section 1.7.3 where comments on the effects of the Proposed Action and noise (and clarification of the analysis) were addressed.
62-78	Please see Section 1.7.3 where comments on the increased use of the incinerator were addressed.

Missoula.) It is clear from the DEIS that all waste that is generated by a BSL-4 is fully decontaminated before leaving the building - thus there is no 'need" for incineration of this waste from a medical waste decontamination standpoint. *A full analysis of this reasonable air pollution prevention mitigation alternative must be included in the DEIS.*

62-79

62-80 The addition of a new emergency power generator will also increase air emissions. Scoping comments specifically requested NIH to consider the use of SCONOX technology to control emissions from the new emergency generator. *This pollution prevention alternative should be discussed in the DEIS.*

5.4.6 Lack of energy conservation strategies.

Energy conservation and increased energy efficiency is not adequately discussed in the DEIS. 40 CFR 1502.16 requires that an EIS disclose:

> "Energy requirements and conservation potential of alternatives and mitigation measures."

The comments on energy consumption in section 2.1.2 simply states that:

> "Several power-saving devices would be incorporated into the proposed facility, including, but not limited to, energy saving equipment and lighting, enhanced insulation, and provisions for a heat recovery system." (DEIS 2-7)

62-81 In addition there is not even a section on energy consumption in the Environmental Consequences chapter. This does not satisfy the NEPA requirements. *A full energy consumption analysis of the preferred alternative must be included in the document. How much energy will be needed to operate the lab? In addition, energy saving conservation alternatives must be presented in the document for comparison.*

5.4.7 Lack of light pollution prevention strategies.

The planned outdoor lighting for the preferred alternative is not addressed in the DEIS, despite specific scoping comments that were submitted regarding a concern about light pollution from the proposed project. There is concern and disappointment in the community regarding the flood lighting currently used on the new BSL-3 building at RML. *Please discuss the planned outdoor lighting for the preferred alternative and the light pollution prevention strategies that will be employed.*

62-82

5.4.8 Lack of hazardous materials use reduction strategies.

The only reference to hazardous substances in the DEIS is a brief paragraph in Section 2.1.2 which states:

> "Use, storage, and disposal of hazardous waste are accomplished in accordance with applicable state and federal regulations. RML is currently stressing waste minimization practices that would also be applied to the Integrated Research Facility. Waste minimization practices include ordering necessary laboratory chemicals in smaller quantities." (DEIS 2-8)

Comment	Response
62-79	Please see response to comment 62-20.
62-80	Please see Section 4.7 where comments on air quality were addressed.
62-81	Please see section 1.7.1 where comments on energy consumption were addressed.
62-82	Please see Section 1.7.3 where comments on impacts associated with lighting were addressed.

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Despite a specific scoping request for detailed information on current and expected chemical use and waste disposal, the DEIS does not include any accounting for the types of hazardous chemicals to be used, how they will be disposed of, or how much increased use there will be with the new lab. *A current chemical use and chemical waste inventory must be included in the DEIS.* (Note: Appendix F: "Chemical Use and Chemical Waste Inventories" of RML's Voluntary Cleanup Plan released by Maxim Technologies in June 2003 would be a good place to start finding this information). *There should also be a section under Environmental Consequences regarding hazardous substances - estimating the increased use and disposal of hazardous substances that will be associated with the preferred alternative. The "waste minimization practices" mentioned in the DEIS should be listed and the extent of the pollution prevention quantified.*

62-83

5.4.9 Lack of water conservation strategies.

The preferred alternative will significantly impact water usage at the facility. *Measures to reduce water consumption and wastewater must be included as pollution prevention alternatives in the DEIS.*

62-84

Comment	Response
62-83	Please see Section 1.7.3 where comments on increased use and disposal of hazardous chemicals were addressed.
62-84	Please see Section 1.7.2 where comments on the pollution prevention strategies were addressed.

6. Failure to Disclose Impacts.

6.1. The DEIS apparently failed to provide an accurate Cost-Benefit Analysis (40 CFR 1502.23).

40 CFR 1502.23 COST-BENEFIT ANALYSIS: If a cost-benefit analysis relevant to the choice among environmentally different alternatives is being considered for the proposed action, it shall be incorporated by reference or appended to the statement as an aid in evaluating the environmental consequences. ...

While perhaps not a "normal" cost/benefit analysis, NIH's DEIS did use the following financial statement to claim that a reasonable alternative suggested by the public could not be feasible: **Construct Integrated Research Facility (BSL-4) at Alternate Location**.

NIH's Rational for Dismissing [in part]: "This alternative also fails to meet the budgetary constraints in the purpose of the Project and the effectiveness and efficiency part of the need for the Project." "Issues addressed through this alternative are also addressed through the No Action Alternative". (DEIS 2-10)

62-85 The above DEIS statement does not appear to be accurate or correct. NIH fails to disclose that there is an already built BSL-4 facility in Bethesda, Maryland. It appears plain that it certainly would be "cost effective" to use it, rather then spend over $66 million dollars on a new BSL-4 lab in Hamilton, Montana. The "no action" alternative does not really apply well either because of the unused Bethesda facility. There's already one existing - there has been a previous "Federal Action" that could completely meet the "Purpose and Need" except apparently that it's not in Hamilton, Montana. It appears that this does not comply with 1502.23 nor does it evidence a hard look and full disclosure.

6.2 Potentially significant adverse impacts were not adequately analyzed, discussed or disclosed as required by the NEPA/CEQ.

6.2.1 "Hard Look" is required by NEPA.

62-86 The DEIS failed to provide any meaningful analysis or disclosure regarding potentials and/or adverse impacts of an escape or release of an agent from the proposed RML BSL-4 facility.

"NEPA ensures that important effects will not be overlooked or understated only to be discovered after resources have been committed or the die otherwise cast." (Robertson v. Methow Valley Citizens for Council, 490 U.S. 332, 342; 109 S. Ct. 1835, 1845 (1989))

Compliance with NEPA occurs only when an agency takes a "hard look" at the environmental consequences of its actions. (Sierra Club v. Kleppe, 427 U.S. 390, 410, n21)

Comment	Response
62-85	Please see Section 1.7.4 where comments on the budget were addressed. Please also see response to comment 62-7.
62-86	Please see Section 1.7.3 where comments on the potential risk were addressed.

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The first criterion that must be addressed is whether or not the agency took a "hard look" at the problem. (Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989); see also, Maryland National Capitol Park and Planning Commission v. United States Postal Service, 487 F.2d 1029, 1040 (D.C. Cir. 1973); Central Audubon Society of Arkansas v. Dailey, 977 F.2d 428, 434 (8th Cir. 1992))

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321, et seq., and implementing regulations promulgated by the Council on Environmental Quality, 40 C.F.R. 1500 et seq., require the preparation of an Environmental Impact Statement for major federal actions that may significantly affect the environment.

62-87 NIH has stipulated that proposing to build a BSL-4 facility at RML is such an action by their preparation of the EIS. Therefore, that EIS must address all significant adverse environmental consequences, direct or indirect, that may be caused by the agency's activities. 42 U.S.C. 4332 (2) (C) (ii); 40 C.F.R. 1502.16; 40 C.F.R. 1508.8.

6.2.2 The DEIS admits that there is a risk to the community, but fails to disclose the consequences.

The NIH's DEIS disclosed the following information:

> "The potential for a release of an agent from RML and the increased likelihood of terrorism as a result of the Proposed Action is reduced by the physical and procedural safety measures inherent to RML and Proposed Action." (DEIS S-3)
>
> **Summary Comparison of Alternatives**
> Proposed Action - Community Safety: "Remote increased risk to the community." No Action - Community Safety: "No increased risk to the community." (DEIS 2-11)
>
> **Environmental Consequences - Community Safety**
> "Potential added risk to the community from the Proposed Action cannot be effectively quantified." (DEIS 4-2)

The DEIS describes the agents that will be studied in the proposed BSL-4 facility as:

> "Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission." (DEIS 1-5)

The NIH says that the potential for release or terrorism is "reduced" (DEIS S-3) but they do not say it is eliminated entirely or that there is no potential whatsoever. The DEIS acknowledges that there is a "remote increased risk" from the Action Alternative, and there is "no increased risk" from the No Action Alternative (DEIS 2-11). The DEIS claims that the "potential added risk" ... "cannot be effectively quantified"(DEIS 4-2).

Comment	Response
62-87	The DEIS, SDEIS, and FEIS do address effects of the Proposed Action and No Action Alternatives. Although the CEQ regulations do state that an EIS must be completed when there would be significant effects, the decision to prepare an EIS does not necessarily mean that significant effects would occur or that all effects would be significant.

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62-88

6.2.3 The DEIS must disclose the consequences of reasonably foreseeable risks.
This is needed even if the probability is assessed to be low. The importance of such an analysis cannot be overstated. Such an analysis is essential for identifying mitigation measures, safety protocols, community health and service needs, health risk to people, risk to wildlife, risk to property values, and risk to businesses. As a minimum, the DEIS should disclose the consequences of the following events:

62-89

6.2.3a Staff infections that are isolated to lab environment.
This should include both those that are isolated to the laboratory and those in which the staff member infects other people. This is certainly a realistic scenario since RML has had recent staff exposure, have been infected and/or carriers in the past, and have infected their spouses.

6.2.3b Staff infections that result in a community wide epidemic.

6.2.3c Release of infections through escaped animals.

6.2.3d Release of infectious prions through the incinerator including an assessment of recombination after cooling in the smokestack.

6.2.3e Release of infectious agents through water via sewage, wetlands, or surface water.

6.2.3f Release of infectious agents through ground due to spills or purposeful dumping.

Cont. on next page

6.2.3g Release of infectious agents when being transported.

6.2.3h Release of infectious agents through water via sewage, wetlands, or surface water.

6.2.3i Release of infectious agents because of an out of control fire.
This is particularly important since RML continually fails fire inspections. (See Appendix B and comments under 6.3).

6.2.3j Release of infectious agents through intentional acts by a staff member.

6.2.3k Release of infectious agents due to a terrorist attack with a bomb or aircraft.

6.2.3l Release of infectious agents due to the safety committee and staff failing to understand the behavior and danger of a new pathogen under study.

Comment	Response
62-88	Please see Section 1.7.3 where comments on risk were addressed.

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62-89

6.2.3m Release of infectious agents due because a HEPA filter fails to stop the agent. See Appendix C for a government report on the failure to test HEPA filters to verify their specified performance. Also analyze HEPA filter failure modes, and operation when incorrectly maintained or used.

6.2.3n Release of infectious agents due to a failure of the safety systems. This should include a Failures and Effects Analysis for each component and the system as a whole.

6.2.3o The causal release environment: accidental spill, fire, terrorist explosion.

6.2.3p Release through steam exhaust.

62-90

6.2.4 Refusal to disclose the risks or consequences to human health is a violation of Federal Regulations.

Essentially, the NIH is saying that they cannot "effectively" determine or express the quantity of the risks or impacts from escape or release of agents. Nor is there any indication they tried. This does not appear to be in compliance with the following CEQ regulations, and especially, the requirement of 1502.22(b)(4).

6.2.4.a NIH is required to assess consequences.

40 CFR 1502.16 ENVIRONMENTAL CONSEQUENCES:

"This section forms the scientific and analytic basis for the comparisons under 1502.14. It shall consolidate the discussions of those elements required by sections 102(2)(C)(i), (ii), (iv), and (v) of NEPA which are within the scope of the statement and as much of section 102(2)(C)(iii) as is necessary to support the comparisons. The discussion will include the environmental impacts of the alternatives including the proposed action, any adverse environmental effects which cannot be avoided should the proposal be implemented, the relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and any irreversible or irretrievable commitments of resources which would be involved in the proposal should it be implemented. This section should not duplicate discussions in 1502.14. It shall include discussions of: (a) Direct effects and their significance (1508.8). (b) Indirect effects and their significance (1508.8). (c) Possible conflicts between the proposed action and the objectives of Federal, regional, State, and local (and in the case of a reservation, Indian tribe) land use plans, policies and controls for the area concerned. (see 1506.2(d).) (d) The environmental effects of alternatives including the proposed action. The comparisons under 1502.14 will be based on this discussion. (e) Energy requirements and conservation potential of various alternatives and mitigation measures. (f) Natural or depletable resource requirements and conservation potential of various alternatives and mitigation measures. (g) Urban quality, historic and cultural resources, and the design of the built environment, including the reuse and conservation potential of various alternatives and mitigation measures. (h) Means to mitigate adverse environmental impacts (if not fully covered under 1502.14(f))."

Comment	Response
62-89	Please see Section 1.7.3 where comments on risk were addressed.
62-90	Please see Section 1.7.3 where comments on risk were addressed.

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6.2.4b DEIS fails to comply with regulations in discussing risk.

40 CFR 1502.22 INCOMPLETE OR UNAVAILABLE INFORMATION:

"When an agency is evaluating reasonably foreseeable significant adverse effects on the human environment in an environmental impact statement and there is incomplete or unavailable information, the agency shall always make clear that such information is lacking. ... (a) ... (b) If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, the agency shall include within the environmental impact statement: (1) A statement that such information is incomplete or unavailable; (2) a statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment; (3) a summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment, and (4) the agency's evaluation of such impacts based on theoretical approaches or research methods generally accepted in the scientific community. For the purposes of this section, "reasonably foreseeable" includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific, is not based on pure conjecture, and is within the rule of reason."

62-91

40 CFR 1508.27 SIGNIFICANTLY:

"Significantly" as used in NEPA requires considerations of both context and intensity: (a) Context. This means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality. Significance varies with the setting of the proposed action. For instance, in the case of a site-specific action, significance would usually depend upon the effects in the local rather than in the world as a whole. Both short and long-term effects are relevant. (b) intensity. This refers to the severity of impact. Responsible officials must bear in mind that more than one agency may make decisions about partial aspects of a major action. The following should be considered in evaluating intensity: (1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial. (2) The degree to which the proposed action affects public health or safety. (3) Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas. (4) The degree to which the effects on the quality of the human environment are likely to be highly controversial. (5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks. (6) The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future action. (7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts significance exists if it is reasonable to anticipate a cumulatively significant

Comment	Response
62-91	Please see Section 1.7.3 where comments on risk were addressed.

> impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts. (8) The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources. (9) The degree to which the action may affect an endangered species or its habitat that has been determined to be critical under the Endangered Species Act of 1973. (10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

The DEIS disclosed that the: "Potential added risk to the community from the Proposed Action cannot be effectively quantified." (DEIS 4-2)

It appears that the DEIS's dismissive treatment of the safety concerns and risks analysis fails to comply with 40 CFR 1502.16, 1502.22, 1502.24, 1508.8 and 1508.27, et seq.

6.2.4c Risk assessment is a common practice of the Federal Government.
In other situations the Federal Government has undertaken a risk assessment even though the probabilities were not firmly defined.

Risk assessments are required in DOD Acquisitions (DOD 2000). For an example of how these methods are applied to RML risks, see Appendix C.

The fact that it is difficult to assess risk in this case does not mean that it is impossible to quantify in an EIS. For example, in the Bison Management Plan for the State of Montana and Yellowstone National Park brucellosis transmission was identified as a potential significant impact within the scope of the EIS. That EIS clearly states (National Park Service FEIS Volume I, page 29) that there has never been a documented transmission of brucellosis between buffalo and cattle: "No documented cases exist of wild, free ranging male bison transmitting brucellosis to domestic cattle." Nevertheless, a detailed analysis of the potential for Yellowstone buffalo to transmit brucellosis to cattle was calculated and included in the EIS (Volume I Environmental Consequences - Impacts on Socioeconomics pages 514-557). *Similarly a full risk analysis of the potential for a release of a BSL-4 agent to the community can and must be included in this DEIS.*

6.2.4d Risk assessment is a stated need in NIH and Biological Safety Principles.
The CDC and NIH document the need (NIH/CDC, 1999) and textbooks on the subject also document the need for risk assessments. (FLEMING, 2000).

6.2.5 Claim that there has never been a "confirmed" release is entirely unsubstantiated.
NIH's DEIS tries to allay the public's concerns about risk, safety, and adverse impacts by unequivocally stating that: "In more than thirty years of working with BSL-4 agents in the U.S., there has never been a confirmed release to the community from a laboratory (Wilson, 2003)." (DEIS 4-2)

The DEIS only later discloses elsewhere, that the Wilson quote was only in the form of a "personal communication"(DEIS L-5).

62-92 The citation to back up the claim is a personal communication with Dr. Deborah Wilson. No explanation of Dr. Wilson's background or occupation other than "OSHB, DS, NIH." These acronyms need to be clarified. In addition, the fact that the oldest BSL-4 in the U.S. at CDC in Atlanta was built in 1978 (just 25 years ago, not 30) the credibility of the "personal communication" is weakened. A more credible source should be cited for this claim, or it should be removed from the document.

6.2.6 There has been a reported terrorist attack using agents traced to a US government BSL-4 Lab.

The press has reported DNA analysis evidence of the anthrax powder that appeared in our nation's capital came from a U.S. government-run BSL-4 lab.

62-93 **6.2.7 The DEIS ignores the fact that the risk of a release of infectious material to the surrounding community will rise significantly with the addition of new laboratories and the increase in frequency of experiments.**

According to our information regarding Dr Fauci's hearing testimony, it appears that there are only three currently operating BSL-4 facilities in the United States; CDC in Atlanta, Georgia; Fort Dietrich, Maryland; and 'one operational in Texas'. (Dr. Fauci; June 10, 2002; Homeland Security)

The 12/15/2000 memo released under the FOIA by NIAID's Mr. Paul Marshall (FOIA Coordinator) appears to place the BSL-4 labs in different locations: "Biosafety level-4 laboratory space in the United States is currently limited to three facilities located in Bethesda and Fredrick, Maryland, and Atlanta, Georgia. One additional facility is planned for construction in Galveston, Texas".

If it is accurate that there are three currently "operating" BSL-4 labs in the United States, then that very small number of operating BSL-4 labs is what the NIH is holding up to demonstrate the BSL-4 lab's 'perfect' safety record.

Additionally, according to a Missoulian newspaper article, the DEIS may have made an error when they stated that BSL-4 labs have operated for 30 years with a perfect safety record: "Karl Johnson, the virologist who built the first BL-4 in 1978 in Atlanta ... said Hamilton and the Bitterroot Valley have nothing to worry about. BL-4 labs are safe, necessary and will allow even better research to go on in Montana." Johnson is on a committee reviewing the design plans for Rocky Mountain Labs' proposed BL-4. (Missoulian State Bureau, 'In the 'Hot Zone'; by Jennifer McKee; September 15, 2002)

62-94 Subtracting 1978, (assuming it even actually "started" in 1978), from 2003 indicates it's really only about 25 years, not 30 years, that the one particular CDC Atlanta lab has been in operation. The DEIS failed to disclose when either of the other two operating BSL-4 labs were built and actually went into operation.

Cont. on next page

Comment	Response
62-92	This information was included in the List of Preparers in the SDEIS. It appears again in the FEIS. Please also see Appendix D, Review of Biocontainment Laboratory Safety Record.
62-93	Please see Section 1.7.3 where comments on risk were addressed.

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62-94

The bottom line is that it is likely that no BSL-4 facility in the U.S. has operated safely for 30 years as was stated in the DEIS.

It appears that only one lab has operated for about 25 years (or less, counting construction time); and, no data has been given for how long the other two existing labs have been in actual operation. Three BSL-4 labs operating 25 years, or likely less, is a very small sample or data base for the NIH's DEIS to use to assume, and/or assure the public of, absolute safety. This does not appear to rise to NEPA's requirement for a "hard look" and "full disclosure".

Some proponents for the new BSL-4 facility in Hamilton have dismissed public concerns regarding the potential risks of constructing the lab.

A newspaper article by the Medford Mail Tribune discussed some of the risk and safety concerns: RML has a long record of discovery and safety. It developed a vaccine for Rocky Mountain spotted fever and discovered the bacterial makeup of tick-borne Lyme disease. However, Dr. Linda Perry, a former employee at RML says that, unlike previous RML research, the work proposed for the new lab will involve mysterious pathogens, such as the flesh-eating Ebola virus about which little is known. "Science has little understanding of how these disease agents are spread," Perry said. "This alone heightens the risk of an employee not realizing he or she is infected and walking out of the lab into the community." Once loosed among unsuspecting residents, Perry says the lab's mystery disease agents could turn Hamilton into a "biological ghost town." (Bio-fear in the Bitterroot Valley; Medford Mail Tribune; by Les AuCoin; Environmental News Service 7/14/03)

In that same article, the newspaper further reported that: ... others say they are willing to be convinced the lab will be safe but the nagging question remains: "Why Hamilton?" Along with many residents of Ravalli County, they suspect, as in the case of the government's storage of radioactive wastes at Hanford, WA and Yucca Mountain, that NIH picked their town because it is geographically remote and politically weak. A Biosafety Level 4 lab was built several years ago on the Bethesda, MD campus of NIH but it has never been used for this purpose. Maryland has a ten-member congressional delegation, more than three times the numerical strength of Montana's contingent. Hundreds of other members of Congress live in Bethesda, an affluent suburb of Washington, D.C. However, opponents used the Freedom of Information Act to access NIH documents concerning Hamilton. One memo cited the town's "rural location" and "sparse population" to suggest that a release of deadly pathogens would not cause "catastrophic damage." "That's an unsigned memo written on a paper with no letterhead," [an RML representative] protested. "You can't associate it with NIH's official attitude." Still, someone at NIH thought those thoughts. .... (Bio-fear in the Bitterroot Valley; Medford Mail Tribune; by Les AuCoin; Environmental News Service 7/14/03)

It appears possible that the Bethesda, Maryland citizens were concerned enough about the BSL-4 facility at NIH that they prevented its use - after it was physically constructed.

Comment	Response
62-94	The DEIS never says that BSL-4 labs have operated for 30 years with a perfect safety record. The DEIS (and FEIS) says that in 30 years of working with BSL-4 agents in the U.S., there has never been a confirmed release to the community from a laboratory. The citation and statement are correct.

Additionally, the 12/15/2000 memo released under FOIA by Mr. Paul Marshall, (FOIA Coordinator, NIAID) raised the disturbing possibility that Hamilton, Montana was a desirable place to build a new BSL-4 lab because "... the RML campus is located in western Montana, well removed from major populations centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster."

Nuclear power plants were once considered fairly safe - until the well-publicized incidents at Three Mile Island, Chernobyl and Hanford. And, it appears that no new nuclear plants have been built in the U.S. since.

6.2.8 With a Ten Fold increase in BSL-4 experiments the probability of a single community release over 25 years can raise over nine times that of the previous 25 years.

62-95

Clearly, the risk of a single release event increases with the number of laboratories and experiments. The DEIS admits that there is a finite risk. The RML and other BSL labs often experience accidents and annually have several staff infections as a group. The risk of at least one release can be high even if the risk associated with current levels is low. For example:

If the risk of an infectious agent a release to the community over a single experiment is *R*. And given that *N* experiments per year are performed. And the probability of release for each experiment is statistically independent then the risk of a single event in a year, then the likelihood of at least one release event in a year *Rs* is:

$Rs = 1 - (1 - R)^N$
If R = 0.0001% and N = 10,000, then Rs = 1% change of at least a single event in one year.

If we assume that the current situation of a few BSL-4 labs operating results in 10,000 experiments (N) per year and that each experiment has a low probability of a single event (R). Then, over 25 years at the above-assumed rates, the odds are 5 to 1 that no event would have occurred.

If the number of experiments are increased 10-fold as seems to be contemplated by the NIAID, then Rs = 9.5% chance of a single event in one year. This would give a high probability of an event in the next 25 years of 92% of at least one release.

Of course this situation could be rectified by increasing safety procedures and reducing the current risk (R) to R`. If R` is one tenth of the current risk, then the probability of an event in the next 25 years would become 22%. This certainly would indicate that extreme safety measures beyond those currently in place would be prudent.

62-96

The DEIS must perform an analysis of the safety risk and examine the impacts of increased experiments in the risk.

Comment	Response
62-95	There is no evidence to support this statement.
62-96	Please see Section 1.7.3 where comments on risk were addressed.

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62-97 **6.2.9 Specific information requested to aid in understanding the analysis.**
Ref. DEIS 2-1 and 2-8. *Who is going to train them and supervise? How much experience do they have?*

62-98 Ref. DEIS 2-2. *Disclose the safety record of HEPA filters and the ability to test their effectiveness to the specifications claimed in the DEIS.*

62-99 *What is the present existing level of treatment at the water treatment plant? Describe and explain in detail.*

62-100 Ref. DEIS 2-8. Laboratory security, "safety policies and procedures would be reviewed whenever an incident occurs or a new threat is identified." *Who would be reviewing the safety and policy procedures? Would the policies and procedures be reviewed more often, absent an incident or event? If there were an incident, would this information be released and/or made available to the public in a timely manner?*

62-101 Ref. DEIS 2-9 and 4-1. *When will the emergency plan be available for review by the public? It should be released as part of the DEIS.*

62-102 Ref. DEIS 2-10. "Relocation would take approximately 10 years and an estimated $1 billion." *How was this estimate made?*

62-103 Ref. DEIS 2-10. *Regarding $66.5 million for construction which has been allocated by Congress, please provide budget line item and, if it is included in a larger line item, to what uses the other allocations will be put.*

62-104 Ref. DEIS 3-4. *What level of training do the security guards currently working at RML have? What level of training and experience would federal security guards have?*

62-105 *Is there a fire protection plan for RML? If so, the DEIS should reference it.*

62-106 Ref. DEIS 3-5. Health Care. *What plan is in place if an employee of RML is exposed to a pathogen? A deadly pathogen? How would the person be transported to the hospital? How would the transportation vehicle be decontaminated after exposed person was transported? How long would a decontamination procedure take and how long would it tie up resources, or be out of commission, due to transport and decontamination?*

62-107 Ref. DEIS 3-5. Transportation. "Nearly 69 percent of recorded collisions occurred on U.S. 93." Note that, according to MDT Annual Safety Report, US Highway 93 has an accident rate significantly better than the other roads in Ravalli County, on average. Thus, the reference here is flawed.

This may not be reassuring since pathogens will most likely be transported via ground shipments and along Highway 93, increasing the likelihood of the transport vehicle getting into a collision and possibly releasing deadly pathogens into the environment or exposing the driver of the transport vehicles and others who may be at the scene of the

Comment	Response
62-97	Please see Section 1.7.1 where comments on the required training for laboratory workers and their supervision where addressed.
62-98	Information on the safety of HEPA filters may be found online at http://www.engr.psu.edu/ae/wjk/fom.html. It discusses single HEPA filters and their efficiencies related to microbial aerosols. The Integrated Research Facility would use double HEPA filtration.
62-99	Please see Section 4.8.1.1 where the Hamilton water system is discussed.
62-100	Please see Section 1.7.1 where comments on safety procedures were addressed.
62-101	Please see Section1.7.2 were comments on the emergency plan were addressed.
62-102	Please see Section 2.2.2.2.
62-103	Please see Section 1.7.4 where issues or concerns outside the scope of the EIS were addressed.

Remainder of responses on following page.

Comment	Response
62-104	All contract security guards must successfully complete training in Basic Security Training Curriculum (training in topics such as firearms safety/handling, vehicle inspection techniques, security patrol methods, search and seizure, enforcing the law, communication, ethics and professionalism), orientation training and supervisory training. Guards and supervisors complete a quarterly refresher training based on basic and orientation training topics. Police officers within the Division of Police must graduate from the Federal Law Enforcement Training Center's Mixed Basic Police Officer Training Program, or a Police Academy that meets the criteria. They must also complete 40 hours of annual in-service training, semi-annual firearms training, security training, specialized training, and supervisor/ management training.
62-105	Please see Section 2.1.1 where fire protection is addressed.
62-106	Please see Section 1.7.1 where requests for additional information on the alternatives were addressed.
62-107	Please see Section 1.7.2 where comments on the emergency plan were addressed.

accident.

6.2.10. Community Safety discussion is misleading.

Section 4.2.1.1 states:

> "…the nature of transmission of many diseases that would be studied at RML provides a natural mechanism controlling their spread in a community." (DEIS 4-5)

The claim being made is that some BSL-4 diseases are those that require an intermediate host or direct contact with infected bodily fluids, which reduces the risk of spread within a community. However, it must be made clear in this section that U.S. government's priority for research in new BSL-4 labs is to study diseases which could be used as an agent of bioterrorism - diseases for which person-to-person aerosol transmission is possible. Section 125 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 states:

> "Section 319F(h) of the Public Health Service Act, is amended to read as follows:
>
> 319 F (h) (2) Priority. --The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures…
>
> (4) Priority countermeasures. --For purposes of this section, the term `priority countermeasure' means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be--
>
> (A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 351A(a)(1), or harm from any other agent that may cause a public health emergency;

62-108 Tick borne diseases, or other diseases which are difficult to transmit person to person are not usually considered diseases which "may cause a public health emergency" and thus are not a priority for funding. *The claim that "many" of these diseases would be studied at RML is therefore misleading and should be removed from the DEIS.*

6.2.11 Impact and risk of lab-acquired infections or diseases for RML workers is not disclosed.

Standard and Special Safety Practices for Biosafety Laboratories (DEIS-Appendix C) as it applies to existing BSL-3 facilities has not prevented lab-acquired infections or occupational diseases for RML employees and scientists.

Poor adherence to lab safety procedures or practices at Rocky Mountain Labs led to an incident in April 2001 involving the exposure of virulent Y. Pestis, the cause of plague, in lab environment and to workers who entered the lab. After the incident, Ted Hackstadt, Chair of Rocky Mountain Lab's Biosafety Committee recommended: "that all work with

Comment	Response
62-108	This assumption that **only** diseases that can be used for bioterrorism would be studied at the Integrated Research Facility because of funding priorities is incorrect. Please see Chapter 1.

virulent Y. Pestis be suspended until it can be carried out in the new facility under strict BL3 containment."

(Ted Hackstadt, PHD Chair RML Biosafety Committee to [name deleted], memorandum on Possible Y. Pestis exposure, April 17, 2001)

As of 1999, there was no national reporting system in place for lab-acquired infections of diseases or illnesses. Two separate lab-acquired diseases and claims for compensation have been made at Rocky Mountain Labs for exposure to Chlamydia and Tuberculosis. An additional employee claim for compensation was filed for lab exposure to Y. Pestis.

(Biosafety in Microbiological and Biomedical Laboratories Manual, U.S. Dept of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health, 4th Edition, May 1999 (Guest Editor: David Hackstadt PHD RML)

Nigel Strozier, Claims Examiner Dept. of Labor, Employment Standards Administration, Officer of Worker's Compensation, Occupational Disease Claim, February 9, 1999.

Employment Standards Administration, Office of Workers Compensation, Occupational Disease Claim, December 7, 2000.

Notice of Occupational Disease and Claim for Compensation, Dept. of Labor, Employment Standards Administration, Office of Workers Compensation, May 3, 2001)

62-109 *Provide a risk analysis of current and projected health impacts of RML workers acquiring infectious disease(s) or being exposed to aerosolized biological agent(s).*

Lab Inspection and NIH Lab Safety Surveys (2000-2002) found numerous examples of poor adherence at Rocky Mountain Labs to standard biosafety practices and inadequate or improperly maintained safety equipment:

- Blocking or obstructing safety features of Biosafety Cabinets and Chemical Fume Hoods
- Disabling audible alarms on Biosafety Cabinets and Chemical Fume Hoods
- Storing chemicals in Biosafety Cabinets
- Storing incompatible chemicals together
- Improperly identifying or not labeling chemicals
- Failing to secure gas cylinders
- Blocking sprinklers
- Blocking pathways
- Failing to provide safety showers, eye and hand wash stations in labs
- Improper placement of safety/biohazard signs on lab doors
- Overfilling sharps containers
- Providing out-of-date fire extinguishers
- Overloading outlets
- Wedging BSL-2 lab doors open

Comment	Response
62-109	Please see Section 1.7.3 where comments on increased risk were addressed.

(LAB INSPECTION SUMMARY 2000; NIH Lab Safety Surveys, 8/25/00; 9/15/00; 7/19/01; 7/23/01; 7/26/01; 7/27/01; 8/1/01; 8/07/01; 7/25/02; 7/30/02; 7/31/02; 8/1/02; and 8/6/02)

In March 1994 a lab worker removed his flow hood while handling Mycobacterium tuberculosis a "pathogenic material highly resistant to anti-tuberculosis drugs." Co-workers informed him that biosafety cabinet exhaust "fan was malfunctioning." The lab worker was unaware of the malfunctioning safety feature as "the audible alarm was disabled since the hoods require so long to balance."

(Clifton E. Barry III Unit Head Mycobacterial Research Unit, LICP, to RML Biosafety Committee, memorandum on Potential Exposure [of name deleted] to Mycobacterium, April 21, 1994.)

In 1996 Rocky Mountain Labs was notified that hospital-grade facemasks for lab workers conducting pathogenic tuberculosis research did not "efficiently filter out aerosolized bacteria."

(Clifton E. Barry III Tuberculosis Research Unit, LICP, RML, DIR, NIH to Biosafety Committee, memorandum on Notification of skin test conversion of [name deleted] and procedural changes in the P-3 facility, August 30, 1996)

6.2.12 Biosafety procedures are inadequate because they are not mandatory.

The safety publications issued by NIH are for guidance only and therefore lack the essential requirement to insure that safety requirements will be complied with. In fact, the failure to impose safety requirements increases the risk of accidents.

62-110

The DEIS should assess the impact on safety in an environment where the staff does not have specific requirements for compliance that is enforced by an independent chain of command.

The DEIS should clearly spell out which requirements are enforced and which are optional.

6.3 Failure to disclose and mitigate Fire Protection, Emergency Planning, Preparedness, Response and Communication Measures.

62-111

The proposed action and no action alternatives fail to adequately disclose and mitigate fire protection, community safety, emergency containment of an infectious agent or hazardous chemical accident at RML. These failures include system inadequacies, planning and preparedness measures, training and provision of equipment to protect the community, emergency responders and lab employees. Emergency response is identified (DEIS 4-5) as a means to "reduce the potential for release of an agent to the environment or community." Yet this aspect of prevention and containment is sorely lacking in

Cont. on next page

Comment	Response
62-110	Please see Section 1.7.3 where comments on increased risk were addressed. Please also see Section 1.7.1 where requests for addition information on the alternatives were addressed.

62-111 analysis of baseline conditions and disclosure of critical information for the public to make informed comments.

RML's Emergency Plan (DEIS 2-9) states that: "Local police, fire, and other emergency responders would be informed of the types of biological materials used in the laboratory and consulted in developing an emergency response plan."

It is unacceptable from a community standpoint to simply "consult" emergency responders in planning contingencies for emergencies at RML's expanded BSL-4 facility.

62-112 *Police, fire fighters, hazardous materials response, medical services personnel are an integral part of community safety and need to be involved in each phase of communicating, planning, preparing, responding, containing and mitigating emergencies that do and will arise at RML. Include the information in a new DEIS.*

RML has failed to adequately describe the full range of existing emergency preparedness and community safety issues as evidenced by statements such as this (DEIS 4-7):

62-113 "Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML." In other words, these procedures and protocols are not currently in place.

A July 2002 Fire Protection Survey Report of RML identified Priority fire prevention, protection and response issues at which resources should be directed to correct these valid concerns. Designation of a Priority fire safety issue presents: "major life safety hazards or conditions which could severely impact on the ability to accomplish vital missions and are those which attention and resources should be directed." Priority fire safety issues identified at Rocky Mountain Labs in July 2002 fire inspector report include:

- Absence of an on-site preventative maintenance program for fire protection systems - fire suppression and fire alarms for all buildings on campus.

- Absence of a formalized fire protection agreement with local fire department for response and abatement of emergencies covering: 1) Emergency forces notification, 2) Incident command structure, 3) Preplanning of target hazards, 4) Joint training efforts, and 5) Replacement of lost and damaged equipment.

- Developing a basic level training program for Fire Brigade commensurate with hazards at Rocky Mountain Labs and expected levels of performance, and provision of personal protective equipment.

- Examining procedures for retransmitting fire alarms to emergency responders. On-site security do not to automatically call Hamilton Fire Department during a fire alarm, instead "off-duty maintenance personnel are paged to investigate the condition."

(Fire Protection Survey Report, July 30, 2002)

Comment	Response
62-111	Please see Section 1.7.2 where comments on the emergency plan were addressed.
62-112	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.
62-113	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.